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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,242		Daniella I. Zheleva	CCI-014CP2	9212

959 7590 12/16/2004

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BOSTON, MA 02109

EXAMINER	
CHISM, BILLY D	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/771,242	ZHELEVA ET AL.	
	Examiner	Art Unit	
	B. Dell Chism	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-51 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-51 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The previous Restriction requirement, mailed 13 August 2004, is withdrawn, as it was mailed while the application had an outstanding Notice of Incomplete Nonprovisional Application. Therefore, the previous Restriction requirement is withdrawn and the current Restriction requirement is as follows:

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

The following inventions (herein referred to as Groups) are divided by SETs of Groups and by individual Groups (not in SETs). The Groups of each set are drawn, in their respective relationship, to the 45 compounds listed in the table of claim 20. The limitation of the Groups in SETs to claim 20 was chosen by the Examiner for the purpose of advancing prosecution, wherein the independent claim 1 is so broad that no reasonable starting point could be acquired without asserting the limitations of claim 20 for purposes of restriction. The compounds are numbered as SEQ ID NOs: 377 and 461-504, totaling 45 structurally and functionally different compounds. Each SET contains 45 Groups with each Group of each SET corresponding in sequence with the compounds of SEQ ID NOs: 377 and 461-504. To illustrate the restriction technique used herein, SEQ ID NO: 377 corresponds to the peptide of Invention 1 of SET 1, it corresponds to the peptide of Invention 46 in SET 2, and it corresponds to the peptide of Invention 91 in SET 3. The election of a SET will not be considered a correct response to the restriction requirement. Applicants are only allowed to elect one Group whether it be an individually listed Group, i.e., Group 137, or one Group from just one SET of Groups, i.e., Applicants could elect just Group 45 of SET 1.

SET 1:

Groups 1-45, Claims 1-24, drawn to a peptide of general formula VI, classified in class 514, subclass 2, for example.

Groups 1-45 are drawn to formulations comprising one of the 45 compound sequences listed in SEQ ID NOs: 377 and 461-504, having different structures and therefore different functions. These formulations are considered to be patentably distinct one from the other. If any one of Groups 1-45 is elected, as defined by each Group's respective compound, the elected Group will be examined only in so far as it pertains to the elected compound from SEQ ID NOs: 377 and 461-504. For example, if Group 1 were elected, then the group would only be examined insofar as it pertains to the corresponding sequence from SEQ ID NO: 377, or if Invention 45 is elected, then it would be considered only insofar as it pertains to the 45th sequence, i.e., SEQ ID NO: 504.

SET 2:

Groups 46-90, Claim 25, drawn to a method for preparing a medicament using a peptide of the general formula VI, classified in class 514, subclass 2, for example.

Groups 46-90 are drawn to methods of making medicaments using formulations comprising one of the 45 compound sequences listed in SEQ ID NOs: 377 and 461-504, having different structures and therefore different functions. These formulations are considered to be patentably distinct one from the other. If any one of Groups 46-90 is elected, as defined by each Group's respective peptide used, the elected Group will be examined only in so far as it pertains to the elected peptide from SEQ ID NOs: 377 and 461-504. For example, if Group 46 were elected, then the group would only be examined insofar as it pertains to the corresponding sequence of SEQ ID NO: 377, or if Invention 90 is elected, then it would be considered only insofar as it pertains to the 45th sequence, i.e., SEQ ID NO: 504.

SET 3:

Groups 91-135, Claims 26-41, 43-44, drawn to an assay for identifying candidate substances capable of binding to a cyclin, using a peptide of the general formula VI, classified in class 514, subclass 2, for example.

Groups 91-135 are drawn to an assay for identifying candidate substances capable of binding to a cyclin using a peptide of general formula VI comprising one of the 45 compound sequences listed in SEQ ID NOs: 377 and 461-504, having different structures and therefore different functions. These formulations are considered to be patentably distinct one from the other. If any one of Groups 91-135 is elected, as defined by each Group's respective peptide used, the elected Group will be examined only in so far as it pertains to the elected peptide from SEQ ID NOs: 377 and 461-504. For example, if Group 91 were elected, then the group would only be examined insofar as it pertains to the corresponding sequence of SEQ ID NO: 377, or if

Invention 135 is elected, then it would be considered only insofar as it pertains to the 45th sequence, i.e., SEQ ID NO: 504.

Group 136. Claims 42-44, drawn to a method of using cyclin in a drug-screening assay, classified in class 530, subclass 350, for example.

Group 137. Claim 45, drawn to a peptide of formula I, classified in class 514, subclass 14, for example.

Group 138. Claim 46, drawn to a peptide of SEQ ID NO: 1, classified in class 514, subclass 15, for example.

Group 139. Claim 47, drawn to a peptide of SEQ ID NO: 2, classified in class 514, subclass 16, for example.

Group 140. Claim 48, drawn to a peptide of formula III/SEQ ID NO: 3, classified in class 514, subclass 16, for example.

Group 141. Claim 48, drawn to a peptide of formula IV/SEQ ID NO: 189, classified in class 514, subclass 16, for example.

Group 142. Claims 49-51, drawn to a peptide of formula V/SEQ ID NO: 293, classified in class 514, subclass 17, for example.

2. The inventions are independent or distinct, each from the other because:

The Groups 1-45 in SET 1 are independent and drawn to compound formulations with different structures and functions and having different end results.

The Groups 46-90 in SET 2 are independent and drawn to methods of using compounds with different structures and functions and having different end results.

The Groups 91-135 in SET 3 are independent and drawn to methods of using compounds with different structures and functions and having different end results.

The Groups of SET 1 and Groups of SET 2 are distinct inventions as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the processes for using the products as claimed can be practiced with other

materially different products or (2) the products as claimed can be use in materially different processes of using that product (MPEP § 806.05(h)). In the instant case the invention Groups of SET 1 can be used for biomolecular markers or in immunoassays.

The Groups of SETs 2 and 3 are independent inventions wherein the two groups of methods are independent, using separate method steps, active agents, and having different effects.

The Groups of SET 1 and Groups of SET 3 are distinct inventions as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the processes for using the products as claimed can be practiced with other materially different products or (2) the products as claimed can be use in materially different processes of using that product (MPEP § 806.05(h)). In the instant case the invention Groups of SET 1 can be used for biomolecular markers or in immunoassays.

The Groups of SET 1 are structurally and functionally different than the products of Groups 137-141.

The Groups 137-141 are structurally and functionally different compounds and therefore distinct inventions.

The Groups of SETs 2-3 comprise method steps that neither make nor use the products of Groups 137-141.

3. Because these inventions are distinct for the reasons given above and the search required for an invention of one set is not required or inclusive for the search of any other invention, thus causing a burden on the Examiner, restriction for examination purposes as indicated is proper.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejections are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above

policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism, whose telephone number is (571) 272-0962. The examiner can normally be reached on M-F 08:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, PhD can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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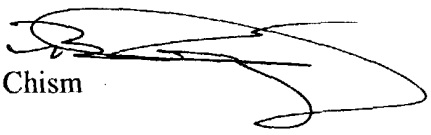

B. Dell Chism

PATENT EXAMINER